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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,970	01/11/2002	Rami Lidor-Hadas	1662/55602	3018

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EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	PAPER NUMBER
1626	
MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/045,970	LIDOR-HADAS ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 5, 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 52-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 52-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3 and 52-54 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 7 (filed January 13, 2003) was acknowledged

in a previous Office Action. The requirement was deemed proper and made FINAL in a previous Office Action.

Response to Amendment

The Declaration under 37 CFR 1.132 filed February 17, 2005 is insufficient to overcome the rejection of claims 1-3 and 52-54 based upon obviousness under 35 USC § 103 over Chen {Zhongguo Yiyao Gongye Zazhi (1993), 24(6), pages 241-242}, Tyers {U.S. Pat. 4,845,115}, Coates et al. {U.S. Pat. 4,695,578} and Tyers {U.S. Pat. 4,835,173} as set forth in the last Office action because: (1) the Declaration states, not shows, that the prior art does not have a purity of at least about 99.0%, see paragraph 2 on page 1; (2) the Declaration states that the product produced in Coates et al. has 0.12% of the exo-methylene whereas Applicant's claim that their product has less than

about 0.01% of the exo-methylene; (3) the Declaration fails to show that the instant claimed product has a viable unexpected, unobvious and superior property, not just of allegedly higher purity; and (4) the Declaration is unclear if the cited prior art were compared with the instant claimed invention, see Table 3, for example.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the specification or the originally filed claims can be found for the phrases “a therapeutically effective amount” or “at least one pharmaceutically acceptable excipient” found in newly added claim 52. Applicant did not indicate {page number(s) and line number(s)} where in the specification support could be found for newly added claims 52-54. Applicant stated that “One of skill in the art recognizes that a "pharmaceutical formulation" refers to a composition comprising an active pharmaceutical ingredient in a therapeutically effective amount and at least one pharmaceutically acceptable excipient.” However, Applicant’s argument is not persuasive since said phrases in question were never apart of the originally filed disclosure. Therefore, the claims lack written description as such.

Response to Arguments

Applicant's arguments filed November 5, 2007 have been fully considered. Applicant argues that: (1) support can be found for claims 52-54 in originally filed claims 45-47; and (2) although originally filed claims 52-54 do not expressly recite "a therapeutically effective amount", one of ordinary skill in the art would recognize that components are inherent in a "pharmaceutical formulation" of Ondansetron hydrochloride dihydrate in view of the knowledge in the art at the time the application was filed, such as the disclosure in U.S. Patent 4,695,578.

All of Applicant's arguments have been considered but have not been found persuasive. It is disagreed that instant claims 52-54 find sufficient written description from originally filed claims 45-47. As acknowledged by Applicant, originally filed claims 45-47 do not recite a "therapeutically effective amount" nor "at least one pharmaceutically acceptable

excipient". Applicant's argument that one of ordinary skill in the art would recognize that components are inherent in a "pharmaceutical formulation" of Ondansetron hydrochloride dihydrate is not persuasive. The specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. *In re Gardner*, 166 U.S.P.Q. 138 (CCPA 1970). Additionally, the disclosure in U.S. Patent 4,695,578 was not incorporated by reference in the instant specification. Therefore, Applicant can not rely on the disclosure in U.S. Patent 4,695,578 to correct the lack of written description for instant claims 52-54. The rejection is deemed proper and therefore, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise

extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 52-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-29 of copending Application No. 11/482,486. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the claims in copending Application No. 11/482,486 is silent as to the purity of the product obtained.

It has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of crystals to secure a pure product. *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946).

Changing the form, purity, color, or other characteristic of an old product without a new use as a result thereof does not render product patentable where utility remains the same. *Ex parte Hartop*, 139 USPQ 525. The compounds are of the same identical formula and as such would be expected to have the same utility. The difference, if any, may reside in there being of a higher purity.

One of ordinary skill in the art would be motivated to prepare a purer form of a known organic pharmaceutically active compound in the expectation of

obtaining that very compound but with enhanced properties, e.g. improved solubility, shelf-life, improved mode of administering properties, etc. In the absence of a showing of a viable unexpected, unobvious and superior property (not just an alleged higher purity), the instant claimed invention is found obvious over the cited prior art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed November 5, 2007 have been fully considered. Applicant states that a response to the obviousness-type double patenting rejection will be deferred until all other issues have been resolved.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen {Zhongguo Yiyao Gongye Zazhi (1993), 24(6), pages 241-242}, Tyers {U.S. Pat. 4,845,115}, Coates et al. {U.S. Pat. 4,695,578}, Tyers {U.S. Pat. 4,835,173} and Lidor-Hadas et al. {WO 02/36558}, each taken alone or in combination with each other when similar utilities are asserted. An English translation of Chen was provided with a previous Office Action and will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims Ondansetron hydrochloride dihydrate. Each of Chen {page 1, Compound (1) and page 2- section III}, Tyers '115 {column 3 and especially Example 2 in column 3}, Coates et al. {column 4 and especially Example 10 in column 20}, Tyers '173 {column 3 and especially Example 2 in column 3} and Lidor-Hadas et al. {page 3, lines 12-21 – Form A} teach Ondansetron hydrochloride dihydrate.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claimed invention and the prior art is that the prior art is silent as to the purity of the product obtained.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

It has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of

crystals to secure a pure product. *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946).

Changing the form, purity, color, or other characteristic of an old product without a new use as a result thereof does not render product patentable where utility remains the same. *Ex parte Hartop*, 139 USPQ 525. The compounds are of the same identical formula and as such would be expected to have the same utility. The difference, if any, may reside in there being of a higher purity.

One of ordinary skill in the art would be motivated to prepare a purer form of a known organic pharmaceutically active compound in the expectation of obtaining that very compound but with enhanced properties, e.g. improved solubility, shelf-life, improved mode of administering properties, etc. In the absence of a showing of a viable unexpected, unobvious and superior property (not just an alleged higher

purity), the instant claimed invention is found obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed November 5, 2007 have been fully considered. Applicant argues that the cited art does not explicitly or inherently disclose or provide any guidance as to the purity of the compound recited in the claim. In response, as stated in the previous Office Action, if mere silence were enough, then every anticipation and/or obviousness could be overcome by simply putting in some limitation that the reference happened to be silent about, even if the material were exactly the same or similar as the prior art. One could add limitations of physiochemical characteristics such as density, color, melting point, solubility in any solvent, etc. and then simply point to the silence of the reference. However, the cited

prior art compounds are of such purity that they are being administered for various pharmaceutical purposes such as treating or relieving nausea, migraines, psychotic disorders (i.e., schizophrenia), depression, cognitive disorders (i.e., dementia), etc. Therefore, Applicant's argument is not persuasive.

Applicant argues that: (1) none of the references teach or provide guidance as to Applicant's two-prong approach that can produce the instant claimed product in the recited purity; and (2) the Rule 132 Declaration of Dr. Lidor-Hadas shows unexpected results. In response, some of the cited prior art teach processes wherein the obtained product is recrystallized with the expectation of obtaining a purer form. It would appear that the novelty **may** lie in the process of making the product, said process not under examination in the instant application, and not the known product itself. Further, the Declaration under 37 CFR 1.132 filed February 17, 2005 has been found insufficient for

reasons stated above. For all the reasons given above, the rejection is deemed proper and therefore, the rejection is maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the

mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton, Ph.D./
Primary Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

February 26, 2008